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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,643	03/10/2006	Tetsuo Kojima	14875-146US1 C1-A0228P-US	8363

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,643	KOJIMA ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

   This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

   In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

   Group I, claim(s) 10, drawn to an antibody having agonistic activity against a cytokine receptor wherein the receptor is the type I interferon receptor comprising an AR1 chain and an AR2 chain and wherein the antibody comprises a variable region of an anti-AR1 chain antibody and a variable region of an anti-AR2 chain antibody wherein the anti-AR1 chain antibody has the amino acid sequence of SEQ ID NO: 1 as the H chain variable region, and the amino acid sequence of SEQ ID NO: 2 as the L chain variable region, and the anti-AR2 chain antibody has the H and L chain variable regions recited in any one of subparts (b1)-(b10) of claim 10.

   Group II, claim(s) 11, drawn to an antibody having agonistic activity against a cytokine receptor wherein the receptor is the type I interferon receptor comprising an AR1 chain and an AR2 chain and wherein the antibody comprises a variable region of an anti-AR1 chain antibody and a variable region of an anti-AR2 chain antibody wherein the anti-AR1 chain antibody has the amino acid sequence of SEQ ID NO: 3 as the H chain variable region, and the amino acid sequence of SEQ ID NO: 4 as the L chain variable region, and the anti-AR2 chain antibody has the H and L chain variable regions recited in any one of subparts (b1)-(b3) of claim 11.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions a priori lack unity of invention in that the claimed antibodies of Groups I and II share no identifiable significant structural element essential to a shared common property or activity other than the fact that all of SEQ ID NOs: represent polypeptides having Ig-type domains which is a property generic to all antibodies regardless of their specificity. For example, compare the Vh and Vl regions of the antibodies of claim 10 subparts (a) and (b1) with the antibodies of claim 11, subparts (a) and (b2) (see attached alignments). But for the Vl regions of the claim 10(b1) and claim 11(b2) antibodies there is no apparent significant structural element conserved among the antigen binding CDR regions of these antibodies and the instant specification does not identify a shared structural element essential to a shared common property or activity.

   Moreover, while the Vl regions of the claim 10(b1) and claim 11(b2) antibodies appear to be very similar, it is well established in the art that the formation of an antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a

given antibody, each of which consists of three specific complementarity determining regions, (CDRs 1-3), which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

For example, Janeway et al. teach that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (See Janeway et al., Immunobiology, 5th Ed., Garland Science, pp. 94-105 (2001)).

Thus, while the Vl regions of the claim 10(b1) and claim 11(b2) antibodies appear to be very similar it is still the case that the claimed antibodies comprise Vh regions having no apparent significant structural element conserved among the antigen binding CDR regions and given the art recognized principal of both Vh and Vl being involved in antigen binding the claimed antibodies are still prima facie lacking unity of invention for the reasons given above.

3. Claims 1-9 and 12 link(s) inventions I and II. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-9 and 12. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election/Restrictions

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

   The species are as follows:

   If applicant elects the invention of Group I, applicant is required to further elect a particular anti-AR2 antibody to be examined from among the anti-AR2 antibody possibilities recited in claim 10, parts (b1)-(b10)

   If applicant elects the invention of Group II, applicant is required to further elect a particular anti-AR2 antibody to be examined from among the anti-AR2 antibody possibilities recited in claim 11, parts (b1)-(b3).

   Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

   Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

   The following claim(s) are generic: 1-12.

   The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: for the same reasons outlined above with respect to the antibodies of Groups I and II.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
May 13, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644